

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-743V

Filed: July 25, 2014

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U.S. COURT OF FEDERAL CLAIMS

RICHARD WILLIAMS-O'BANION,

PUBLISHED

Special Master
Hamilton-Fieldman

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Decision on the Record; Insufficient
Proof of Causation; Vaccine Act
Entitlement; Denial of Compensation
Without Hearing; RCFC Rule 8(d).

Respondent.

Richard Williams-O'Banion, Pro Se, Rancho Cordova, CA, Petitioner.

Lara Englund, United States Department of Justice, Washington, DC, for Respondent.

DECISION¹

On October 20, 2008, Richard Williams-O'Banion ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("the Program"), 42 U.S.C. §300aa-10 *et seq.* (2006),² alleging that he suffered neurological injuries caused by

¹ The undersigned intends to post this Decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by Vaccine Rule 18(b), each party has 14 days within which to file a motion for redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). In the absence of such motion, the entire decision will be available to the public. *Id.*

² The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§300aa-10 *et seq.* (2006). Hereinafter, individual section references will be to 42 U.S.C. §300aa of the Vaccine Act.

receipt of an influenza (“flu”) vaccination on October 28, 2005. Petition (“Pet”) at 1, ECF No. 1. For the reasons set forth below, the undersigned finds that the record does not support entitlement to an award under the Program.

I

PROCEDURAL HISTORY

An Initial Order was issued in the case on November 18, 2008. Order, ECF No. 4. Petitioner was originally represented by the Homer, Conway & Chin-Caplan law firm. Pet. at 1.

Petitioner’s counsel filed a Motion to Withdraw as Attorney of Record on July 31, 2009. Motion, ECF No. 19. During the next year, no filings were made in this case. However, on August 5, 2010, Petitioner’s counsel filed a status report, outlining the status of the case. Petitioner’s counsel stated that he had mailed Petitioner several letters, explaining why Petitioner’s counsel would no longer remain on the case. Status Report at 1, ECF No. 21. Petitioner’s counsel had additionally contacted another experienced Vaccine Program attorney to see if she was interested in representing Petitioner, and on June 9, 2010, the attorney notified Petitioner’s counsel that she was not interested in representing Petitioner. *Id.* at 1-2. Petitioner’s counsel then sent Petitioner a follow-up letter, asking him how he wished to proceed with the case; the letter requested that Petitioner contact Petitioner’s counsel’s office “*posthaste.*” *Id.* at 2. Telephone messages were left for Petitioner on July 6th, 16th, and 30th, 2010. *Id.* at 2. On August 4, 2010, Petitioner’s counsel again called Petitioner. A message on the telephone indicated that Petitioner’s telephone number had either changed or was disconnected. *Id.* at 2.

On September 7, 2010, the special master granted Petitioner’s counsel’s Motion to Withdraw as Attorney of Record. Order, ECF No. 23. The special master ordered Petitioner to inform the court of how he wished to proceed with his case by no later than February 7, 2011. Order, ECF No. 24. The special master’s order was returned to the court as undeliverable. Notice, Jan. 4, 2011, ECF No. 26.

Petitioner’s failure to respond to the September 7 order prompted the special master to issue an Order to Show Cause, which instructed Petitioner to provide the court with a valid address, telephone number, and a determination of how Petitioner wished to proceed with his claim. Order, ECF No. 27. The mail was again returned to the court as undeliverable (Notice, Apr. 8, 2011, ECF No. 28); however, on May 9, 2011, Petitioner submitted a current address to the court and indicated that he wished to proceed as a *pro se* Petitioner. Response, ECF No. 29.

On September 9, 2011, Respondent’s counsel filed a Rule 4(c) Report, stating that “[t]here is no evidence in the record that petitioner’s neurological symptoms were caused by the flu vaccine he received in October 2005.” Report at 25, ECF No. 33. The special master ordered Respondent to revise this Rule 4 (c) Report by putting all information into numbered paragraphs.

Order, ECF No. 37. Respondent's counsel filed a revised Rule 4(c) Report on October 31, 2011. Report, ECF No. 36.³

Eleven months later, Petitioner filed a Response to Respondent's Report. Response, ECF No. 45. Petitioner was thereafter ordered to file an expert report in pursuit of his claim. Order, Aug. 24, 2010, ECF No. 46. Specifically, Petitioner was ordered to file an expert report from his treating physician, Dr. William R. Work, M.D., by no later than November 30, 2012. Order, ECF No. 50.

Petitioner did not file the letter of Dr. William R. Work, M.D. until February 19, 2013. Notice, ECF No. 53. Upon reviewing Dr. Work's letter, the special master found that Dr. Work did not conclude why or how Petitioner's injury occurred, nor did Dr. Work explain the medical records upon which he relied in asserting that Petitioner's neurological symptoms began one day following vaccination. The special master submitted additional questions regarding Petitioner's claim to Dr. Work for further clarification.

The case was reassigned to the undersigned on March 18, 2013, pursuant to Vaccine Rule 3(d). Order, ECF No. 55. Three months later, Petitioner filed Dr. Work's Responses to the court-ordered questionnaire. Response, June 12, 2013, ECF No. 59. Dr. Work's responses did not provide evidence of a biological mechanism or scientific theory causally connecting Petitioner's vaccination with his injury, nor did Dr. Work's answers provide any basis for his conclusion concerning a date of onset one day following vaccination.

When questioned at a status conference, Petitioner failed to explain where evidence existed in the record, denoting the onset of his symptoms one day following vaccination. EDR Recording of Status Conference, Jul. 16, 2013, 2:16:21-2:18:50; Minute entry, Jul. 16, 2013. Petitioner concluded, "[w]hat I have is the response to VAERS⁴ that I've sent and the notations from my doctor [Dr. Work] stating the symptoms that immediately followed." *Id.* at 2:18:30-2:20:00. The undersigned reiterated the concern that there were a number of visits to medical providers in the period following vaccination, but no information in the record to show any

³ The undersigned has reviewed the extensive medical records filed in this case; however, because Respondent's Rule 4(c) Report contains a medical record summary that constitutes a comprehensive summary of those extensive medical records, the undersigned does not herein provide another such summary.

⁴ VAERS ("Vaccine Adverse Events Reporting System") is a database created, pursuant to the Vaccine Act, by the FDA and the Centers for Disease Control and Prevention to receive reports about adverse events which may be associated with vaccines. *See* Vaccine Adverse Event Reporting System, available at <https://vaers.hhs.gov/about/index>. *See also* *Nance v. Sec'y of Health & Human Servs.*, No.06-0730V, 2010 WL 3291896, at *9 (Fed. Cl. Spec. Mstr. July 30, 2010) (discussing that VAERS is a surveillance system that accepts "voluntarily submitted" reports of events from manufacturers, health care workers and patients, and that the experiences reported are unsolicited and reflect the reporting party's concern of a possible relationship to vaccination).

neurological injury until February of 2006. *Id.* During this status conference, the undersigned also asked Petitioner if Dr. Work planned on filing anything else into the medical record in this case. Petitioner stated that “[Dr. Work] was very stressed and is still very stressed out over the letters . . . he tried to make himself as clear as possible as far as . . . his perception [or] any doctor’s perception.” *Id.* at 2:15:00-2:16:00. When questioned as to if Petitioner would be retaining a medical expert in this case, Petitioner stated that he would not be retaining one. *Id.* at 2:27:00-2:27:30. Respondent’s counsel then suggested that the next move in the case would be for Respondent to file a Motion for Summary Judgment since no expert report would be filed, and Respondent’s counsel believed that the only evidence establishing vaccine causation concerned timing, which is not sufficient under the law. *Id.* at 2:31:00-2:32:00. The undersigned then explained the proposed filing procedure to Petitioner to see if he was amenable to proceeding forward in this way; Petitioner consented to proceeding forward with the case in this fashion because he wanted a resolution of this case. *Id.* at 2:32:00-2:37:40.

The undersigned thereafter ordered Respondent to file a Motion for Summary Judgment, Petitioner to file a Response to that Motion, and Respondent to file a Reply. Order, ECF No. 61. Respondent’s Counsel filed a Motion for a Ruling on the Record on August 16, 2013. Motion, ECF No. 62. On December 3, 2013, Petitioner filed his Response to Respondent’s Motion for a Ruling on the Record. Notice, ECF No. 72. Respondent filed a Reply in support of the Motion for a Ruling on the Record on January 14, 2014. Reply, ECF No. 75. This case is now ripe for a decision on the record.

II

DISCUSSION

To receive compensation under the Program, a petitioner must prove either: (1) that the petitioner suffered a “Table Injury” -- i.e., an injury included in the Vaccine Injury Table -- corresponding to his vaccination, or (2) that the petitioner suffered an injury that was actually caused by his vaccination. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). To establish causation-in-fact, the petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. § 300aa-13(a)(1)(A). The petitioner is required to prove that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010) (quoting *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). Pursuant to Rule 8(d) of the Rules of the Court of Federal Claims (“RCFC”), “[t]he special master may decide a case on the basis of written submissions without conducting an evidentiary hearing.” RCFC 8(d).

In the seminal case of *Althen v. Secretary of the Department of Health and Human Services*, the Federal Circuit set forth a three-prong test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1279 (Fed. Cir. 2005). The *Althen* test requires the petitioner to set forth: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the

injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Id.* To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

Specifically, under the first prong of *Althen*, petitioners must offer a scientific or medical theory that answers in the affirmative the question “can the vaccine(s) at issue cause the type of injury alleged?” *See Pafford v. Sec’y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004) (emphasis added). This may be accomplished in a number of ways. *Id.* “Reliability and plausibility of pathogenesis can be bolstered by providing evidence that at least a sufficient minority in the medical community has accepted the theory, so as to render it credible.” *Id.* In addition, epidemiological studies and an expert’s experience, while not dispositive, lend significant credence to the claim of reliability; articles published in respected medical journals, which have been subjected to peer review, are also persuasive. *Id.* However, publication “does not necessarily correlate with reliability,” because “in some instances well-grounded but innovative theories will not have been published.” *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593–94 (1993).

In addition to showing that the vaccine at issue can cause a particular injury, a petitioner must also prove that the vaccine actually *did* cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4 (emphasis added); *Althen*, 418 F.3d at 1279. A petitioner does not meet this obligation by showing a temporal association between the vaccination and the injury; petitioner must explain how and why the injury occurred. *Pafford*, 2004 WL 1717359, at *4.

While a temporal association alone is insufficient to establish causation under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. For example, if petitioner’s theory involves a process that takes several days to develop after vaccination, an injury that occurred within a day of vaccination would not be temporally consistent with that theory. Conversely, if the theory is one that anticipates a rapid development of the reaction post-vaccination, the development of the alleged injury weeks or months post-vaccination would not be consistent with that theory. The special master cannot infer causation from temporal proximity alone. In fact, it has been held, that where a petitioner’s expert views the temporal relationship as the “key” indicator of causation, the claim must fail. *See Thibaudeau v. Sec’y of Health & Human Servs.*, 24 Cl. Ct. 400, 403 (Fed. Cl. Oct. 23, 1991); *see also Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144 (Fed. Cir. 1992); *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983) (stating that inoculation is not the cause of every event that occurs within a ten-day period following it).

A petitioner who demonstrates by a preponderance of the evidence that he suffered an injury caused by vaccination is entitled to compensation, unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994).

In this case, Petitioner sought redress for his injury under the Vaccine Act’s compensatory provision for off-Table injuries. The undersigned examined Petitioner’s medical

records and did not find any evidence that satisfies the three elements of causation set forth above. Petitioner has not proven that the influenza vaccination *can* cause or *did* cause his alleged neurological injury. The undersigned will outline below why Petitioner failed to satisfy all prongs of *Althen* and is not entitled to compensation under the Program.

A. *Althen* Prong I

Under the first prong of *Althen*, Petitioner is required to set forth a reliable medical theory, explaining how a particular vaccination *can* cause a particular injury. *Althen*, 418 F.3d at 1279. Scientific certainty is not required to establish causation under the Vaccine Act. *Id.* at 1280 (indicating that the purpose of the Vaccine Act's preponderance of the evidence standard "is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body"). However, a causation theory accepted by a special master must be supported by a "sound and reliable" medical or scientific explanation. *Knudsen*, 35 F.3d at 548.

In this case, the evidence submitted by Petitioner consists of medical records, a letter from Petitioner's personal treating physician, Dr. William R. Work, M.D., Dr. Work's responses to Special Master Moran's questionnaire, and a report from VAERS. None of this evidence demonstrates a sound and reliable scientific theory connecting the influenza vaccination to Petitioner's neurological injury. The closest that Petitioner gets to establishing a causal theory is through Dr. Work's responses to a questionnaire, regarding the basis of Dr. Work's opinion of Petitioner's claim. In response to the question about his own personal opinion as to the cause of Petitioner's polyneuropathy, Dr. Work stated:

There is no exact test that "proves" a vaccine polyneuropathy. You can test for neuropathy and you can test for the extent of the neuropathy, but the cause of the neuropathy can rarely ever be determined definitively. . . . So my opinion that it is a vaccine neuropathy is quite simple. . . . On October 28, 2005, [Petitioner] was documented to have received an influenza vaccine (while undergoing the anti-viral therapy) at Kaiser Permanente. His symptoms started the following day [Since he] began having disabling symptoms the day following the influenza vaccine and was later diagnosed with neuropathy and the symptoms that he has are the same as those found on VAERS for people suffering with vaccine polyneuropathy, then the simplest answer is the most likely one, i.e., [Petitioner's] polyneuropathy was from the influenza vaccine. . . .

Response (Ex. 1) at 2, ECF No. 59.

This is an argument based solely on the temporal connection between Petitioner's receipt of the vaccine and the alleged onset of his neurological symptoms. It offers no scientific explanation for the alleged correlation between the influenza vaccine and polyneuropathy from which Petitioner suffers. Absent a valid scientific theory connecting the influenza vaccination to

Petitioner's injury, an asserted temporal association alone is insufficient to establish entitlement to compensation under the Vaccine Program. *Moberly*, 592 F.3d at 1323. There can be no assessment of whether the timing of an injury is consistent with a causal theory where no causal theory is presented. While Dr. Work concludes that given the temporal association between vaccination and alleged onset of injury, Petitioner's injury was vaccine-caused, Dr. Work's opinion does not promulgate any medical, scientific, or biological mechanism by which an influenza vaccination *can* cause a neurological injury. Dr. Work's opinion focuses solely on the temporal association between vaccination and injury in this case, which does not satisfy the first prong of *Althen*.

Dr. Work's reliance on VAERS's data to establish prong one of causation is also misplaced. Although it is undisputed that Petitioner suffers from polyneuropathy, the reliability of VAERS data has often been called into question under the Vaccine Program. *See Analla v. Sec'y of Health & Human Servs.*, 70 Fed. Cl. 552, 558 (Fed. Cl. 2006) (discussing "concerns about the reliability of VAERS data"); *Ryman v. Sec'y of Health & Human Servs.*, 65 Fed. Cl. 35, 40, 43 (Fed. Cl. 2005) (VAERS reports may be biased toward pre-existing notions of adverse events); *Capizzano v. Sec'y of Health & Human Servs.*, 63 Fed. Cl. 227, 231 (Fed. Cl. 2004) (VAERS data has limited value due to the manner in which it is collected, the lack of confirmation of the reported information, and the lack of any systematic analysis); *Manville v. Sec'y of Health & Human Servs.*, 63 Fed. Cl. 482, 494 (Fed. Cl. 2004) (VAERS reports can be filed by anyone, thus raising questions about the quantity and quality of the information gathered). Therefore, VAERS data alone, without the opinion of a credible medical expert or without medical records, is not proof of a causal connection.

Finally, under the Vaccine Act, lack of medical literature directly connecting vaccination and injury is not dispositive with regard to establishing causation. *Althen*, 418 F.3d at 1280; *see also Daubert*, 509 U.S. at 593 (acknowledging that there are circumstances in which "well-grounded but innovative theories will not have been published"). While published medical literature linking vaccination to injury is thus not a necessary requirement under the first prong of *Althen*, it is one means of establishing or reinforcing a scientific explanation of causation. *Pafford*, 2004 WL 1717359, at *4. Here, Petitioner has neither promulgated a scientific theory of causation, nor has Petitioner filed any medical literature linking the influenza vaccination to his neurological injury. Without a theory, supportive medical records, or medical literature postulating a theory, there is no evidence in the record that provides a theory of vaccine causation under *Althen* Prong I. As such, Petitioner's claim fails under the first prong of *Althen*.

B. *Althen* Prong II

Under the second prong of *Althen*, Petitioner is required to establish "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1280; *see Capizzano*, 440 F.3d at 1327 ("There may well be circumstances where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine."). The Federal Circuit has also affirmed the notion that an expert opinion, connecting vaccination

with alleged vaccine-related injury, is no better than the soundness of the reasons supporting it. *See Perreira v. Sec'y of Health & Human Servs.*, 33 F.3d 1375 (Fed. Cir. 1994). In this case, Petitioner relies on medical records, the report of his treating physician, Dr. Work, and VAERS data to attempt to establish that logical nexus in this case.

Dr. Work's letter states that the onset of Petitioner's neurological symptoms began the day after Petitioner received the flu vaccination. *See* Response (Ex. 1) at 2, ECF No. 59. The medical records, however, simply do not support this assertion. Despite the undersigned's and the previous special master's numerous attempts to have either Petitioner or Dr. Work point out the medical records that establish this one-day onset, no such records have ever been produced. Instead, the documented onset of Petitioner's neurological symptoms occurred many months after his October 28, 2005 vaccination. Onset of injury is not noted in the medical records until February 2006, when Dr. Charles C. Fang, M.D., noted that Petitioner presented with complaints of "diffuse joint pains," "fatigue," and "achiness." Pet'r's Ex. 2 at 114, 116.

When questioned at a status conference about the onset issue, Petitioner failed to explain this discrepancy. EDR Recording of Status Conference, Jul. 16, 2013, 2:16:21-2:18:50; Minute entry, Jul. 16, 2013. When Petitioner was questioned about any record of neuropathy or fatigue between the time of vaccination and his alleged onset of injury, Petitioner could point to no record documenting such complaints; Petitioner only pointed to the VAERS report he submitted and Dr. Work's letter. EDR Recording of Status Conference, Jul. 16, 2013, 2:16:21-2:24:00; Minute entry, Jul. 16, 2013. Petitioner concluded, "[w]hat I have is the response to VAERS that I've sent and the notations from my doctor stating the symptoms that immediately followed." *Id.* at 2:18:30-2:20:00. The undersigned reiterated the concern that Petitioner had several medical appointments with several medical providers in the months following vaccination, and that none of the records from those visits document neurological symptoms. Petitioner responded to the undersigned on this point by stating, "[t]hey were trying to split up my symptoms individually and would not comment on my symptoms as a whole until they were forced to by VAERS and my insurance company." *Id.* at 2:25:50-2:25:54. Despite the undersigned's attempts at eliciting any evidence of the onset of injury one day following vaccination, the undersigned found no such onset.

Dr. Work stated that the basis for his statement regarding the onset of symptoms one day after Petitioner received the influenza vaccination came from Dr. Work's examination of the medical records from Kaiser, and the letter from Dr. Charles Fang, dated June 13, 2006. Dr. Work acknowledged that Dr. Fang attributed all of Petitioner's neuropathy symptoms to hepatitis C, but Dr. Work disagreed with that attribution. Rather, Dr. Work asserted that Petitioner was able to work full-time without any impairment at his job as a loan officer up until the day the influenza vaccine was administered (October 28, 2005), after which Petitioner was excused from work from November 1, 2005, to June 13, 2006. Response (Ex.1) at 2-3, ECF No. 59. Despite Dr. Work's assertion on this point, there is no evidence in the record showing that Petitioner's time-off work slips indicated that he was not working due to neurological symptoms. If this is the only evidence (Petitioner's time-off work slips) that Dr. Work has to evaluate the onset of Petitioner's injury, then his assessment is speculative at best. Speculation does not amount to proof of causation by a preponderance of the evidence.

The report of Dr. Work does little more than establish that Petitioner had a neurological injury of unknown etiology. Response, ECF No. 59. Dr. Work states that the basis for his opinion regarding Petitioner's polyneuropathy diagnosis was from the records of Dr. Michael O'Brien and Dr. Barry Mann. Response (Ex. 1) at 3, ECF No. 59. Dr. Work stated that both sets of records included nerve conduction testing and both reported a polyneuropathy of unknown etiology. *Id.* Dr. Work maintained that it is simply the juxtaposition of the vaccine and the onset of symptoms combined with the nerve testing that "leads one to more likely than not conclude that Mr. O'Banion's polyneuropathy was caused by the influenza vaccine." *Id.* As discussed earlier, this is a temporal connection, not a causal one. "[N]either a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Moberly*, 592 F.3d at 1323-34 (citing *Althen*, 418 F.3d at 1278).

The fact that at the time Petitioner was seeking treatment for his neurological symptoms, several of Petitioner's doctors, and Petitioner himself at times, attributed his symptoms to hepatitis C or to his treatment for that condition, also does not support Petitioner's argument that his condition was caused by the vaccine. *See, e.g.*, Pet'r's Ex. 2 at 114, 116, 117-19, 127-28; Pet'r's Ex. 5 at 13; Pet'r's Ex. 9 at 10-11; Pet'r's Ex. 10 at 1; Pet'r's Ex. 19 at 46, 51, 53; Pet'r's Ex. 20 at 94-96; 207-10; *see also Curcuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525 (Fed. Cir. 1993) (medical records created contemporaneously with the events they describe are presumed to be accurate; a person seeking treatment will report symptoms and other relevant information accurately and completely to facilitate receiving appropriate treatment).

Finally, Petitioner relied heavily on the VAERS data he submitted in this case to establish a causal link between his vaccination and injury. As the undersigned has previously discussed, the reliability of VAERS data has often been called into question under the Vaccine Program. *See Capizzano*, 63 Fed. Cl. at 231 (VAERS data has limited value due to the manner in which it is collected, the lack of confirmation of the reported information, and the lack of any systematic analysis); *Manville*, 63 Fed. Cl. at 494 (VAERS reports can be filed by anyone, thus raising questions about the quantity and quality of the information gathered); *Ryman*, 65 Fed. Cl. at 40, 43 (VAERS reports may be biased toward pre-existing notions of adverse events); *Analla*, 70 Fed. Cl. at 558 (discussing "concerns about the reliability of VAERS data"). VAERS data alone, without the opinion of a credible medical expert and medical records, attempting to make a rational causal connection between that data and the vaccine and injury alleged, is not proof of a causal connection. Here, VAERS data cannot be used to demonstrate a logical sequence of cause and effect between Petitioner's influenza vaccination and neurological injury, absent direct evidence in the medical record to establish such a connection.

Since Petitioner has provided no evidence that his influenza vaccine did cause his neurological injury, through the medical records or the opinion of a credible medical expert, Petitioner's claim fails under the second prong of *Althen*.

C. Althen Prong III

Under the third prong of *Althen*, Petitioner is required to show that there was a proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1279. Petitioner submitted records that purport to establish a temporal association between when Petitioner received the influenza vaccination and the onset of his neurological injury. Petitioner, however, has not shown a proximate, temporal relationship between the vaccination and alleged injury, since it is not clear when the onset of Petitioner's symptoms first began. Petitioner first complained of "brain fog" in February 2006 (Pet'r's Ex. 2 at 114, 116); his first complaint of weakness and difficulty walking was in March 2006 (Pet'r's Ex. 2 at 120-22); and his first complaint of numbness and tingling was in May 2006 (Pet'r's Ex. 2 at 128-31). These incidents took place many months after his October 2005 vaccination.

Additionally, when discussing his medical history, Petitioner stated multiple times in the record that some of his alleged symptoms had started years prior to vaccination. *See* Pet'r's Ex. 2 at 5-8, 136-37, 141-43; Pet'r's Ex. 5 at 13; Pet'r's Ex. 19 at 46-48, 51, 53; Pet'r's Ex. 20 at 94-96, 207-10. The process for finding facts in the Vaccine Program begins with analyzing the medical records. 42 U.S.C. § 300aa-11(c)(2). Medical records that are created contemporaneously with the events they describe are presumed to be accurate. *See Curcuras*, 993 F.2d at 1528. Petitioner's history of neurological symptoms, as noted in the medical records, pre-date vaccination. This fact alone does little to bolster Petitioner's claim that onset of symptomatology began one day following receipt of the influenza vaccination. *See* Pet'r's Ex. 2 at 5-8, 136-37, 141-43; Pet'r's Ex. 5 at 13; Pet'r's Ex. 19 at 46-48, 51, 53; Pet'r's Ex. 20 at 94-96, 207-10.

Finally, as previously discussed, whether the neurological issues Petitioner attributed to the vaccine began one day after the vaccine or several months after the vaccine is in some ways irrelevant. Petitioner has provided no theory against which to evaluate the temporal nexus of onset. In the absence of that nexus, Petitioner's claim fails under the third prong of *Althen*.

III

CONCLUSION

Under the Act, a petitioner may not be given a Program award based solely on a petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 13(a)(1). In this case, because there are insufficient medical records supporting Petitioner's claim, a medical expert opinion must be offered in support, establishing a biological theory linking vaccination to alleged injury, and demonstrating a logical sequence of cause and effect between said vaccination and injury. Petitioner, however, has not offered a credible or persuasive expert opinion.

The undersigned is sympathetic to the fact that Petitioner suffers from neurological injuries. However, under the law, the undersigned can authorize compensation only if a medical

condition or injury either falls within one of the “Table Injury” categories, or is shown by medical records or a competent medical opinion to be vaccine-caused. No such proof exists in the record. **Thus, this case is dismissed for insufficient proof. In the absence of a timely-filed motion for review of this decision (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.**

IT IS SO ORDERED.

A handwritten signature in black ink, appearing to read 'Lisa D. Hamilton-Fieldman', is written over a horizontal line.

Lisa D. Hamilton-Fieldman
Special Master